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July 8, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2004N-0133 – Electronic Records; Electronic Signatures; Public Meeting

Dear Sir or Madame,

As brief introduction, I am a Senior Manager in the Corporate Compliance and Regulatory Affairs department with responsibility for the Medtronic 21 CFR Part 11 Compliance Program.

Medtronic is actively involved in Part 11 activities through AdvaMed and has provided Part 11 comments through that channel. We are pleased that FDA has provided us with this opportunity to directly provide comments and suggestions concerning the regulation.

In opening, Medtronic requests that FDA remain consistent with the August 2003 document; "Guidance for Industry Part 11 - Scope and Application". In particular, re-emphasizing predicate rules, narrowing scope, and introducing risk assessment for a limited number of requirements are encouraging steps.

Further, in the spirit of the "Scope and Application" guidance, we encourage FDA to consider additional changes to the regulation summarized in our two attached documents that would serve to further simplify the regulation and achieve FDA's stated goals of 1) not unnecessarily restricting the use of electronic technology, 2) not significantly increasing the costs of compliance, and 3) not discouraging innovation and technological advancement.

Our first document contains responses to the "Topics for Discussion" posed in the FDA Public Meeting Notice. The second document contains several additional comments directed toward other specific sections of Part 11.

Finally, we would like to express our concern that opening up Part 11 to rule making may potentially introduce additional requirements beyond those referenced in the "Scope and Application" guidance. We are not in favor of adding requirements and if this should occur, we would oppose retroactive application of new requirements to systems that have been implemented prior to the publish date of the new regulation.

We appreciate FDA's consideration of our opinions and suggestions.

Sincerely,

Michael Benda
Senior Project Manager